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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,145	08/22/2003	Bong Cheol Kim	DE-1501	8727
1109	7590	10/29/2007	EXAMINER	
ANDERSON, KILL & OLICK, P.C. 1251 AVENUE OF THE AMERICAS NEW YORK, NY 10020-1182			LAMM, MARINA	
ART UNIT		PAPER NUMBER		
1617				
MAIL DATE		DELIVERY MODE		
10/29/2007		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/646,145	KIM ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Marina Lamm	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 May 2007.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 38,40-72 and 110-145 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 38, 40-72 and 110-145 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. §.119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Acknowledgment is made of the amendment filed 5/3/07. Claims pending are 38, 40-72 and 110-145. Claims 38, 52, 53, 60, 67 and 68 have been amended. Claims 39 and 73-109 have been cancelled. Claims 110-145 have been newly added.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 38, 40-72 and 110-145 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 38, 60, 67, 68, 113, 135 and 136 as amended or newly presented introduce new matter as they use the phrase "reduce the risk [of allergic disease or non-allergic inflammatory disease in a mammal]". There is no support in the specification for the employment of the phrase "reduce the risk [of allergic disease or non-allergic inflammatory disease in a mammal]" in the claims. The limitation "reduce the risk of allergic disease or non-allergic inflammatory disease in a mammal" was not described in the application as filed, and persons skilled in the art would not recognize in the Applicant's disclosure a description of the invention as presently claimed. The

instant specification discloses that the claimed hardy kiwifruit extract decreased allergen specific IgE and increased allergen specific IgG2a, thus increasing anti-allergic treatment efficiency. See Example 2 on pp. 24-25. The instant specification also discloses that the claimed extract increased Th1 cytokines and decreased Th2 cytokines, thus contributing to alleviation of allergic inflammation. See Example 3 on p. 26. The claimed extract also inhibited histamine release and had anti-inflammatory activity comparable to indomethacin. See Examples 5-6 on pp. 27-28. However, the instant specification does not disclose or even mention the claimed "reduction of the risk of allergic disease or non-allergic inflammatory disease in a mammal". Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor has possession of the subject matter of the amendment at the time of filing of the instant application.

Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, the Applicant is invited to point out to the parts of the specification which provide sufficient written support for the above-mentioned limitation. See MPEP 714.02 and 2163.06.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 38, 40-59, 62, 65-67, 110-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (US 6,630,163), of record, in view of Endres et al. (DE 19758090 A1, Abstract<sup>1</sup>) and/or Udagawa (JP 61140510 A, Abstract<sup>2</sup>).

Murad teaches a method of treating dermatological disorders, including those of inflammatory nature such as inflammatory dermatoses, with fruit extracts, including kiwi fruit extract. See col. 8, lines 10-29. The fruit extract is present in an amount of 0.01-80 wt. %. See col. 8, lines 13-16. With respect to Claims 48-50, Murad teaches the same amounts of the extract. While broadly teaching "kiwi fruit", Murad does not explicitly teach the claimed species of kiwi fruit. However, Endres et al. and Udagawa show that extracts of the claimed species of kiwi fruit are known in the art and used in cosmetics and pharmaceuticals. See respective Abstracts. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use *Actinidia arguta*, *Actinidia kolomikta* or *Actinidia polygama* of Endres et al. or Udagawa for compositions of Murad for their art-recognized purpose with a reasonable expectation of achieving the desired cosmetic results. Selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection. See e.g., *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). With respect to Claims 41-44, Murad does not explicitly teach the kind of extract as claimed herein. However,

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<sup>1</sup> Translation of this document is not available at this time, but will be mailed to the Applicant with the next Office Action, or upon request, after 11/25/07.

Udagawa teaches crude extracts. See Abstract. The crude extract of kiwi fruit is soluble in both water and alcohol because it's a juice. With respect to Claims 51-59, these claims are in a product-by-process format and as such as not limited to the extracts produced by a recited method. A claim to a composition defined by reference to the process by which it is produced, is not limited to compositions produced by the process recited in the claim. See *Scripps Clinic & Research Foundation v. Genentech, Inc.* (CAFC 1991) 927 F2d 1565, 18 PQ2d 1001. Process limitations cannot impart patentability to a product which is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985) 771 F2d 695, 227 USPQ 964.

5. Claims 38, 40-64, 69-72, 110-135, 137-139 and 142-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forastiere et al. ("Consumption of fresh fruit rich in vitamin C and wheezing symptoms in children", Thorax 2000, 55: 283-288), cited by the Applicant, in view of Endres et al. (DE 19758090 A1, Abstract<sup>3</sup>) and/or Udagawa (JP 61140510 A, Abstract<sup>4</sup>).

Forastiere et al. teach consumption of kiwi fruit reduced the occurrence of asthmatic symptoms, which might be attributed to an anti-inflammatory action of vitamin C. See pp. 283, 285. Consuming kiwi fruit as a food meets the limitation "crude extract" of the instant claims. Further, with respect to Claims 70 and 143, kiwi fruit is

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<sup>3</sup> Translation of this document is not available at this time, but will be mailed to the Applicant with the next Office Action, or upon request, after 11/25/07.

<sup>4</sup> Translation of this document is not available at this time, but will be mailed to the Applicant with the next Office Action, or upon request, after 11/25/07.

known to contain sugars. Furthermore, the kiwi fruit juice extracted during eating the fruit is liquid and is soluble in water and alcohol. While broadly teaching "kiwi fruit", Forastiere et al. do not explicitly teach the claimed species of kiwi fruit. However, Endres et al. and Udagawa show that extracts of the claimed species of kiwi fruit are known in the art and used in cosmetics, food and pharmaceuticals. See respective Abstracts. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use *Actinidia arguta*, *Actinidia kolomikta* or *Actinidia polygama* of Endres et al. or Udagawa for method of Forastiere et al. with a reasonable expectation of achieving the desired therapeutic results. Selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection. See e.g., *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). With respect to Claims 51-59 and 126-134, these claims are in a product-by-process format and as such as not limited to the extracts produced by a recited method. A claim to a composition defined by reference to the process by which it is produced, is not limited to compositions produced by the process recited in the claim. See *Scripps Clinic & Research Foundation v. Genentech, Inc.* (CAFC 1991) 927 F2d 1565, 18 PQ2d 1001. Process limitations cannot impart patentability to a product which is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985) 771 F2d 695, 227 USPQ 964. With respect to Claims 45-47 and 120-122, Forastiere et al. do not explicitly teach the concentration of the extract. However, it is believed that if the entire fruit is a

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"composition", the fruit juice extracted during eating the fruit would constitute roughly from one third to half of the entire fruit, depending on its ripeness, and, therefore, meet the concentration limitations of the instant claims.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Response to Arguments***

6. Applicant's arguments filed 5/3/07 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

7. No claims are allowed at this time.

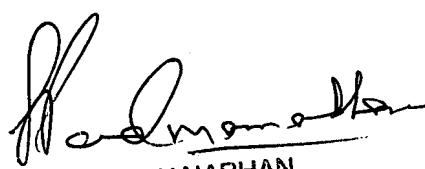
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private

PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm, M.S., J.D.  
Patent Examiner  
10/25/07

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER